§ 168.85

- (iii) Confidentiality claims. Persons submitting the information specified in the purchaser acknowledgement statement may assert a claim of business confidentiality by marking the information claimed confidential "FIFRA Confidential Business Information." Information so claimed will not be disclosed, with the exception of disclosure to the foreign governments, except in accordance with the procedures set forth in 40 CFR part 2, 7 U.S.C. 136(h), and this policy statement. If such claim is not asserted, EPA may disclose the information to the public without providing further notice prior to disclosure or an opportunity to object. Notwithstanding any claim of confidentiality, the purchaser acknowledgement statement will continue to be forwarded to the appropriate foreign government officials in its entirety, as required by section 17(a)(2).
- (3) Recordkeeping. Except as specifically stated, the requirement to retain records under part 169 of this chapter applies to all pesticide producers, regardless of whether a particular product is intended for export. All records shall be maintained in accordance with the time period required by §169.2(h) of this chapter. Producers must also maintain certain records pertaining to pesticide products intended for export. In addition to the requirement that a copy of the purchaser acknowledgement statement be kept, as stated at §169.2(h)(3) of this chapter, the following records must be maintained:
- (i) Copies of the instructions provided to foreign purchasers in accordance with paragraphs (c)(2)(i)(A) and (c)(2)(ii)(A) of this section.
- (ii) Copies of signed purchaser acknowledgement statements obtained according to paragraphs (c)(2)(i)(B) and (c)(2)(ii)(B) of this section.
- (iii) Copies of the certification from the exporter; and copies of any accompanying information regarding the identity of coded R&D products.
- (d) Agency transmission of purchaser acknowledgement statements. EPA will transmit a copy of each purchaser acknowledgement statement to the appropriate government official in each of the intended destination countries. After receipt of the Annual Summary

the following calendar year, EPA will also transmit a copy of that document to the appropriate government official in each of the intended destination countries. In the case that no Annual Summary has been received within 30 days of the date at which such summary is required to be submitted, EPA will send written notification to the appropriate government official indicating that no summary was submitted, and may also take enforcement action against the exporter.

§ 168.85 Other export requirements.

This section describes other requirements found in regulations that apply to exporters of pesticides, devices, and active ingredients used in producing a pesticide.

- (a) Recordkeeping and inspection. Exporters of pesticides, devices and active ingredients must keep records and permit inspections of those records in accordance with part 169 of this chapter. Exporters must keep records of the product labeling used, including the EPA registered labeling, any foreign labeling on or attached to the product when shipped, and, as applicable, any supplemental labeling used. Producers of pesticides for export shall maintain these records in a manner that shows exactly which labels and labeling accompanied each shipment of a pesticide product to a foreign country. As stated at §168.75(c), when research product identity information appears on the labeling in an encoded manner, information translating the code shall be maintained in records. These records shall be maintained for the time period required by §169.2(h) of this chapter following the last export of such pesticides. All records required by part 169 of this chapter shall be made available for inspection and copying by EPA or its duly authorized representatives.
- (b) Pesticide production establishment requirements. Exporters of pesticides, devices, and active ingredients must submit annual reports to EPA in accordance with part 167 of this chapter, concerning those products that are exported. All products required to be labeled "Not Registered for Use in the

Environmental Protection Agency

United States of America' must be reported as unregistered production regardless of whether a purchaser acknowledgement statement is required.

PART 169—BOOKS AND RECORDS OF PESTICIDE PRODUCTION AND DISTRIBUTION

Sec.

169.1 Definitions.

169.2 Maintenance of records.

169.3 Inspection.

AUTHORITY: 7 U.S.C. 136f and 136w.

SOURCE: 45 FR 54338, Aug. 15, 1980, unless otherwise noted.

§ 169.1 Definitions.

Terms used in this part shall have the meanings set forth for such terms in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. In addition, as used in this part, the following terms shall have the meanings set forth below:

- (a) Amount of pesticide or active ingredient. The term "amount of pesticide or active ingredient" means the weight or volume of the pesticide or active ingredient used in producing a pesticide expressed as weight for solid or semisolid products and as weight or volume of liquid products.
- (b) Batch. The term "batch" means a quantity of a pesticide product or active ingredient used in producing a pesticide made in one operation or lot or if made in a continuous or semi-continuous process or cycle, the quantity produced during an interval of time to be specified by the producer.
- (c) Device. The term "device" means any device or class of device as defined by the Act and determined by the Administrator to be subject to the provisions of the Act.
- (d) Inability. The term "inability" means the incapacity of any person to maintain, furnish or permit access to any records under this Act and regulations, where such incapacity arises out of causes beyond the control and without the fault or negligence of such person. Such causes may include, but are not restricted to acts of God or of the public enemy, fires, floods, epidemics, quarantine restrictions, strikes, and unusually severe weather, but in every

case, the failure must be beyond the control and without the fault or negligence of said person.

(e) *Producer*. The term "producer" means the person, as defined by the Act, who produces or imports any pesticide or device or active ingredient used in producing a pesticide.

§ 169.2 Maintenance of records.

- All producers of pesticides, devices, or active ingredients used in producing pesticides subject to this Act, including pesticides produced pursuant to an experimental use permit and pesticides, devices, and pesticide active ingredients produced for export, shall maintain the following records:
- (a) Records showing the product name, EPA Registration Number, Experimental Permit Number if the pesticide is produced under an Experimental Use Permit, amounts per batch and batch identification (numbers, letters, etc.) of all pesticides produced. In cases where the product is an active ingredient used in producing a pesticide or where the product is a pesticide which is not registered, is not the subject of an application for registration, or is not produced under an Experimental Use Permit, the records shall also show the complete formula. The batch identification shall appear on all production control records. These records shall be retained for a period of two (2) years.
- (b) Records showing the brand names and quantities of devices produced. These records shall be retained for a period of two (2) years.
- (c) Records showing the following information regarding the receipt, by the producer, of all pesticides, devices, and active ingredients used in producing pesticides:
- (1) Brand name of the pesticide or device, or common or chemical name of the pesticide active ingredient;
 - (2) Name and address of shipper;
 - (3) Name of delivering carrier;
 - (4) Date received; and
 - (5) Quantities received.

These records are not intended to cover receipt of pesticides used for in-plant maintenance, extermination, or sanitation programs, etc. Shipping and receiving documents such as invoices, freight bills, receiving tickets, etc.,